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June 29, 1999  
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DOCKETS MANAGEMENT BRANCH (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

SUBJECTS: (1) irradiation of foods as in Docket #908N-1038 "Irradiation in the production, processing and handling of food."  
(2) use of recombinant bovine growth hormone (rBGH)  
(3) increasing use of anti-biotics for cows and poultry

As a physician and registered pharmacist, teachers, and fellow consumers, my wife and I have recently become aware that the US - FDA is planning to remove all current labeling requirements for irradiated food. We have learned that the FDA has approved irradiation for essentially all foods, including fruits and vegetables. Facilities have already been built and more are being planned to do this. The labeling requirement has been the sole impediment to this next step in the adulteration of our food supplies. Irradiation has powerful friends in the food processing and nuclear industries, medical establishment and the Federal government. It is a quick, but temporary, fix to the growing problem for poor slaughterhouse sanitation. It is also a way to dispose of nuclear wastes by selling them to private industry and leaving taxpayers with the inevitable clean-up costs.

We feel it is important for the FDA to continue to demand prominent labeling with the terms "irradiation" or "irradiated" used as well as the radura symbol. Equally disturbing and misleading are the use of proposed alternative terms such as "cold pasteurization" and "electronic pasteurization." Irradiation in any form destroys vitamins and causes changes in sensory and spoilage qualities that are not obvious or expected by the consumer.

In addition to this serious problem, we have been advised that the use of recombinant bovine growth hormone (rBGH) has not properly been investigated and reported to the public. In late 1993, the US Food and Drug Administration gave permission for Monsanto Corporation to market rBGH, a genetically engineered hormone that is injected into cows to increased their production of milk. They based approval on an unpublished Monsanto study of rats fed rBGH in high doses for 90 days is hardly proof enough that this hormone is safe for human consumption. Furthermore, no other country will allow the use of rBGH. Approval was denied to Monsanto in the European Union, Australia, New Zealand, and Canada. If these countries are leery of this practice, why aren't we???

A Canadian research report refuted Monsanto's safety studies and concluded that 20 to 30% of the rats developed primary antibody responses as well as cysts on the thyroids of the male and increased infiltration of the prostate gland. In the U.S. tens of thousands of US dairy cows are injected with rBGH each week with consumers being exposed to this hormone by the consumption of dairy products. The trade name is POSILAC and in cows it has been associated with increases in cystic ovaries, disorders of the uterus, digestive problems, enlarged hocks and lesions of the knee, mastitis. Furthermore, POSILAC has been shown to release a chemical called IGF-1 (insulin-like growth factor # 1) which recent studies have demonstrated is linked to prostate cancer in men. McGill University and the Harvard School of Public Health have recently found a four-fold increase risk of developing prostate cancer among men with high levels of IGF - 1 in their bodies.

To top this off, widespread use of rBGH will increase the amount of rendered animal protein that farmers use to feed dairy cattle. Statistics show that a minimum of 14% of the remains of rendered cattle

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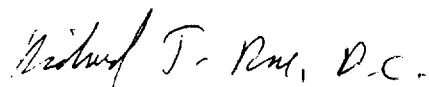
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is fed to other cows, which then increases the risk of Mad Cow Disease. Americans consume 2.6million pounds of dairy cattle annually. Elevated IGF-1 is now being linked to breast cancer, prostate cancer, colon cancer, acromegaly, hypertension, diabetes, and gynecomastia (growth of breasts in men). With cancer statistics and other diseases already on the rise, where is this all heading?

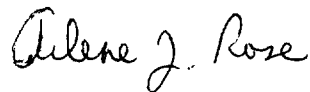
As if this were not bad enough--another risk factor is that the utilization of POSILAC in cows leads to the increasing use of antibiotics for cows. Once more this gets into the human food chain. The poultry industry is already over-utilizing hormones and anti-biotics as well. The Center for Disease Control now tells us that antibiotic resistance is an all time high and now a "major public health crisis."

As a doctor, pharmacist, and teacher, I am appalled at this onslaught of chemicals into our environment and diet. More and more diseases are being linked to these chemical additives and other pollutants in our environment. My wife, also a former teacher, now suffers severe environmental allergies and a compromised immune system. We now both fervently protest this increasing adulteration of our precious food commodities and environment. We urge the use of common sense and a return to safe practices of food production and preparation. We are sharing this information with everyone we know in the hope that other consumers will likewise protest. We hope you will respond responsibly to these important health issues. Good health practices are cost effective as well. In the long run, we will have a healthier populace and less expenses for health care if we approach this issue with the respect that it truly deserves.

Yours truly,



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CROSS FILE SHEET

FILE NO: 98P-1194/C 168

SEE FILE NO: 99P-0485/C 1092

98N-1038/C 3196